

I. Amendments to the Claims

This listing of claims shall replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-74 (canceled)

Claim 75. (currently amended): A dosage form comprising:
particles, the particles consisting of comprising

(a) ~~a therapeutically active agent consisting essentially of an opioid antagonist;~~
and

(b) ~~means for sequestering the opioid antagonist such that the opioid antagonist is substantially not released when the dosage form is orally administered intact as compared to the dosage form that has been tampered with; and~~

(c) one or more optional pharmaceutical excipients;
the means sequestering the opioid antagonist such that an amount of the opioid antagonist released from the dosage form which has been orally administered intact is insufficient to produce a physiological effect of the opioid antagonist in a human patient, and such that an amount of the opioid antagonist released from the dosage form which has been subjected to tampering will produce a physiological effect;

wherein the tampering is by crushing, shearing, grinding, chewing, dissolving in a solvent, heating, or any combination thereof; and

wherein the dosage form is an oral dosage form.

Claim 76. (currently amended): The dosage ~~from~~ form of claim 75, wherein the means for sequestering comprise ~~comprises~~ a layer comprising a hydrophobic material.

Claim 77. (currently amended): The dosage form of claim 75, wherein the means for sequestering comprise ~~comprises~~ from about 93% to about 98% of a hydrophobic material by weight of the particles ~~composition~~.

Claim 78. (currently amended): The dosage form of claim 75, wherein the opioid antagonist is naltrexone, naloxone, nalmefene, cyclazacine, levallorphan, a pharmaceutically acceptable salts or mixtures ~~salt or a mixture~~ thereof.

Claim 79. (currently amended): The dosage form of claim 75, wherein the ratio of the amount of antagonist released from ~~said the dosage form composition~~ after tampering to the amount of ~~said the~~ antagonist released from ~~said the~~ intact dosage form composition is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of ~~said the dosage form composition~~ in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C.

Claim 80. (currently amended): The dosage form of claim 75, further comprising an opioid agonist in a releasable form, which is separate from ~~said the particles comprising a therapeutically active agent consisting essentially of an opioid antagonist.~~

Claim 81. (currently amended): The dosage form of claim 80 which provides immediate release of ~~said the~~ opioid agonist when the dosage form composition is orally administered.

Claim 82. (currently amended): The dosage form of claim 75 which provides sustained release of ~~said the~~ opioid agonist when the dosage form composition is orally administered.

Claim 83. (previously presented): The dosage form of claim 75 which does not pose a risk of precipitation of withdrawal in opioid tolerant or dependent patients when the dosage form is orally administered intact.

Claim 84. (currently amended): The dosage form of claim 75, wherein the opioid antagonist is not bioavailable when the dosage form is administered intact but is bioavailable when the dosage form is tampered with.

Claim 85. (currently amended): The dosage form of claim 75, wherein the physiologic effect is prevention of euphorigenic effects of opioids or development of physical dependence to opioids ~~said tampering is by means selected from the group consisting of crushing, shearing, grinding, chewing and dissolution in a solvent in combination with heating.~~

Claim 86. (previously presented): The dosage form of claim 75, wherein ~~said~~ the tampering is by crushing.

Claim 87. (new): An oral dosage form comprising:
particles, the particles comprising

- (a) an opioid antagonist, and
- (b) means for sequestering the opioid antagonist;

the means sequestering the opioid antagonist such that an amount of the opioid antagonist released from the dosage form which has been orally administered intact is insufficient to produce a physiologic effect of the opioid antagonist in a human patient, and such that an amount of the opioid antagonist released from the dosage form which has been subjected to tampering will produce a physiological effect;

wherein the tampering is by crushing, grinding, chewing, dissolving in a solvent, heating, or any combination thereof;

the particles being free from an opioid agonist.

Claim 88 (new): The dosage form of claim 87, wherein the physiologic effect is prevention of euphorigenic effects of opioids or development of physical dependence to opioids.

Claim 89 (new): The dosage form of any of claims 75, 76, 78, 79, 80, 81, 82, and 87, wherein the sequestered opioid antagonist is adapted to release less than 15% by weight of the opioid antagonist within 36 hours after administration.

Claim 90 (new): The dosage form of claim 89, wherein an amount of the antagonist released from the dosage form which has been administered intact is less than an amount bioequivalent to 0.125 mg of naltrexone, based on the in-vitro dissolution at 1 hour of the dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C.

Claim 91 (new): The dosage form of any of claims 75, 76, 78, 79, 80, 81, 82, and 87, wherein an amount of the antagonist released from the dosage form which has been administered intact is less than an amount bioequivalent to 0.125 mg of naltrexone, based on the in-vitro dissolution at 1 hour of the dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C.